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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,482	03/30/2004	Paula Olhoft	600.479US2	4796

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EXAMINER
BAUM, STUART F

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
06/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
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Office Action Summary	Application No.	Applicant(s)	
	10/813,482	OLHOFT ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 0209*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-64,67,68,71-76 and 78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-64,67,68,71-76 and 78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and Rule 132 Declaration filed 4/6/209 have been entered.

RCE Acknowledgment

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/6/2009 has been entered.

3. Claims 57-64, 67-68, 71-76 and 78 are pending and are examined in the present office action.

Claims 1-56, 65-66, 69-70 and 77 have been canceled.

4. Rejections and objections not set forth below are withdrawn.

Enablement

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 57-64, 67-68, 71-76 and 78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for the stable transformation of monocot plant tissue or cells comprising co-culturing on solid media monocot plant tissue or cells, with Agrobacterium containing a recombinant DNA, wherein the solid media comprises a sulfhydryl-containing agent, wherein said agent enhances stable transformation of the monocot plant tissue or cells relative to corresponding monocot plant tissue or cells without said agent, wherein if the sulfhydryl-containing agent is cysteine, cysteine is present at a concentration of 100 mg/L, or wherein the agent is glutathione, sodium thiosulfate or dithiothreitol; or a method for the stable transformation of plant tissue or cells comprising selecting an amount of cysteine at least 100 mg/L in solid co-cultivation media, and regenerating a plant, or wherein transformation efficiency is at least 10% greater, or at least 0.5% greater, or enhanced by at least 5-fold, or wherein transformed tissue or cells are identified by a selectable or detectable marker, or wherein

the plant tissue or cells are maize, wheat or rice tissue or cells, or wherein the plant tissue or cells are sugarcane.

Applicants have not reduced to practice their invention. Applicants specification does not disclose concentrations of cysteine or any sulfhydryl containing agent that would produce the desired result given the teachings of unpredictability as disclosed in the Jones Declaration. For example, the Jones Declaration discloses that 100 mg/L cysteine did not enhance transformation of *Brachypodium distachyon* (a monocot grass) (page 2 of Jones Declaration, #6). The Jones Declaration also discloses that concentrations of cysteine of 300 mg/L and 350 mg/L were most effective at enhancing transformation of Canon and Bobwhite 56 wheat varieties and that lower and higher concentrations did not result in a significantly different effect or resulted in an inhibitory effect (paragraph #7 that bridges pages 2-3 of Jones Declaration). For corn, the Jones declaration discloses that 150 and/or 300 mg/L enhanced transformation (page 3 of Jones Declaration, #8). Lastly, the Jones Declaration teaches the unpredictable nature of using sulfhydryl-containing agents together in plant transformation. For example, the Jones Declaration discloses combinations of 300 mg/L cysteine with 100 mg/L ascorbic acid and 150 mg/l cysteine with 153 mg/l glutathione decreased inbred corn transformation efficiency relative to embryos treated with the individual agents (page 3 of Jones Declaration, #9). The Jones Declaration teaches the unpredictable nature of using cystein with other media constituents. For example, 300 mg/L cystein with 1.27 mg/L silver nitrate resulted in a decrease in hybrid corn transformation efficiency as compared to 150 mg/L cysteine with 1.27 mg/L silver nitrate. Finally, the Jones Declaration teaches a decrease in inbred transformation efficiency was

observed when 300 mg/L cysteine was used with 100 mg/L ascorbic acid relative to 300 mg/L cystein alone (*Ibid*).

The state-of-the-art teaches that specific conditions and chemical components are required to achieve a successful transformation of a plant. Hansen et al (1999, Trends in Plant Science 4(6):226-231) teach that successful transformation of plants demands that certain criteria be met (page 227, under "Transformation systems"). Some of the requirements are that target tissues are competent for propagation or regeneration, an efficient DNA delivery method, and the ability to recover fertile transgenic plants at a reasonable frequency. Hansen et al also teach that there are variables that need to be tested to ensure success. These variables include the use of feeder cells, alternative *Agrobacterium* strains, infiltration of the bacteria, and the duration and temperature of co-cultivation (page 228, right column, 3rd paragraph). Hansen also teaches that some crops appear to react or be hypersensitive to *Agrobacerium* and form necrotic barriers. To overcome this reaction, the addition of antioxidants is required (page 228, right column, last paragraph).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to test and evaluate the multitude of possible cysteine concentrations either alone or in combination with other sulfhydryl-containing agents and to test different monocot plants or any plant, all of which require different sulfhydryl concentration requirements, to find those, if any that increase transformation efficiencies when compared to transformation efficiencies of control plants.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicant's arguments filed 4/6/2009 have been fully considered but they are not persuasive.

Applicants contend media and target explants to transform a wide variety of plants were known in the art prior to Applicants' filing date, and Applicants list references (page 5 of Remarks, 5th paragraph).

The Office invites Applicants to submit the references in an Information Disclosure Statement for the Office to consider.

6. Claims 57-64, 67-68, 71-76 and 78 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method for the stable transformation of monocot plant tissue or cells comprising co-culturing on solid media monocot plant tissue or cells, with Agrobacterium containing a recombinant DNA, wherein the solid media comprises a sulfhydryl-containing agents, wherein said agent enhances stable transformation of the monocot plant tissue or cells relative to corresponding monocot plant tissue or cells without said agent, wherein if the sulfhydryl-containing agent is cysteine, cysteine is present at a concentration of 100 mg/L, or wherein the agent is glutathione, sodium thiosulfate or dithiothreitol; or a method for the stable transformation of any plant tissue or cells comprising selecting an amount of cysteine at least 100 mg/L in solid co-cultivation media, and regenerating a plant, or wherein transformation efficiency is at least 10% greater, or at least 0.5% greater, or enhanced by at least 5-fold, or

wherein transformed tissue or cells are identified by a selectable or detectable marker, or wherein the plant tissue or cells are maize, wheat or rice tissue or cells, or wherein the plant tissue or cells are sugarcane.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
June 19, 2009